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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,480	01/04/2002	Gregor Cevc	56822 (47126)	5210

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EXAMINER	
FORTUNA, ANA M	
ART UNIT	**PAPER NUMBER**
1723	

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,480	CEVC ET AL.	
	Examiner	Art Unit	
	Ana M Fortuna	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,6-8,35-41,60,61,66-69 and 102-116* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3, 4, 6-8, 35-41, 60, 61, 66~~69~~, 102-116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 7/21/04 has been entered.

Claim Rejections - 35 USC § 112

2. Claims 6, 61, 66, 67, 102 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 is unclear as to whether the terms within the parenthesis are intended to be part of the claim limitation. Claim 6 is also unclear as to whether "hereto-aggregates having a diameter smaller than the diameter of homo-aggregates..." is intended.

In claim 61, in line3-4, there is not closing parenthesis to the one starting after "–buthylphenol (". The term e.g. is incomplete as to what is intended or what elements it encompasses. The terms e.g. are also unclear, as to whether the claim should be limited to the limitation following the term. In claim 66, the term "preferably belonging to the class..." is unclear as to whether the lipids belong to the phospholipids types; the

term "typically" is also unclear as to whether the compounds following the term are part of the claimed limitation. In the later claim, the terms in parenthesis are also confusing. I claim 68, the terms "preferably", "specially", etc., "esp", e.g. render the claim confusing as to what limitations are intended. Claim 102 also include the term e.g. and terms on parenthesis limiting the previous composition, which renders the claim unclear.

3. Regarding claims 61, 67, 102, the phrase "such as" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). See claim 61, lines 2, 10, 21, 222, 23, 24, 30, See claim 67, lines 13, 19, 21. See claim 102, line 69, 11.

4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 61, 66, 67 recites the broad recitation "tocopherols", "flavonoids" and the claim also recites chacones, etc., and

tocopheryl acrylate... In claim 66, the term "lipid, and preferably "phospholipids. which is the narrower statement of the range/limitation. In claim 67, the term the "surfactant as or surfactant like material", and also include "nonionic...."

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 3, 6, 7, 35, 60, 61, 66, 67, 68, 69, 102, 103, 111, 112, 113, 114-115, 116 rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/17255 (hereinafter '255). Reference '255 substantially discloses the product e.g. membrane or barrier containing an active ingredient, and the controlled administration of the ingredients through the barriers (page 1, lines 1-15, page 4, lines 1-21), the active ingredient or composition to be transferred or controlled through the barrier or membrane or skin as claimed in claim 3, 35, and 62 is disclosed in '255 (page 5, lines 15-38, page 6, lines 3-27). The membrane or barrier of size, and pore size as claimed in claim 40, is disclosed in '255 (page 5, lines 15-25, page 12, 12, lines 36-38, and column 13, lines 1-12). The pH of the composition or formulation as claimed in claims 1, 35, 62, 103, 104, is also disclosed (page 12, lines 13-23).

As to claims 6-7, 60, 61, 66, 67, 68, 69, 02, the formulation composition, including all the properties claimed are disclosed in reference '255 (page 6, lines 25-39, page 7, lines 1-39, and page 8, lines 1-39, e.g. peptidespentadecanoyl, palmytoylglycerophophonolipids, etc. the composition including the percentages claimed in claim 69, 114-115, is also disclosed in '255 (page 9, last paragraph, bridging page 10, first paragraph).

Reference '255 discloses the barrier or membrane materials (page 12, lines 1-3).

The tendency to the substances in the composition to aggregate seems to be inherent of the composition. The barrier pore size indicates semi permeability of the fluid composition through the barrier (membrane) pores.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 3, 4, 6-8, 35, 41, 60-61, 66-69, 102-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/17255 (hereinafter '255) in view of Unger (6,028,066) (hereinafter '066). Reference '255, discussed above teaches '255 substantially discloses the product e.g. membrane or barrier containing an active ingredient, and the controlled administration of the ingredients through the barriers

(page 1, lines 1-15, page 4, lines 1-21), the active ingredient or composition to be transferred or controlled through the barrier or membrane or skin as claimed in claim 3, 35, and 62 is disclosed in '255 (page 5, lines 15-38, page 6, lines 3-27). The membrane or barrier of size, and pore size as claimed in claim 40, is disclosed in '255, (page 5, lines 15-25, page 12, 12, lines 36-38, and column 13, lines 1-12).

The pH of the composition or formulation as claimed in claims 1, 35, 62, 103, 104, is also disclosed (page 12, lines 13-23).

As to claims 4, 6-8, 60, 61, 66, 67, 68-100-102, the formulation composition, including all the properties claimed are disclosed in reference '255 (page 6, lines 25-39, page 7, lines 1-39, and page 8, lines 1-39, e.g. peptidespentadecanoyl, palmytoylglycerophophonolipids, etc. the composition including the percentages claimed in claim 69, 107, 108, 114-115, is also disclosed in '255 (page 9, last paragraph, bridging page 10, first paragraph).

Reference '255 discloses the barrier or membrane materials (page 12, lines 1-3).

The membrane made with backing layer made of the polymeric materials as claimed in claims 36 and 41 **are not disclosed** in reference '255.

Reference '066 discloses the process and composition and patch having the composition or medicament as claimed in the present invention, the formulation or composition is provided in a vesicle or compartment defined by membrane walls, the membrane walls are made of polymers such as urethane (column 18, second paragraph, abstract, column 32, last paragraph, through column 33, lines 1-40, and

column 82), the membrane provided with the composition and forming a patch is also disclosed (page 882, second paragraph, through line 60, and page 83, lines 61-64). The composition or formulation including lipids, and amphiphilic substances is also disclosed (column 11, second paragraph, through line 68, and column 12, first two paragraphs).

It would have been obvious to one skilled in the art at the time the invention was made to provide a chamber or vesicle with a semi-permeable membrane containing a formulation to be released through the membrane, as disclosed in reference '255 and '066, an further select the membrane or vesicle or liner defining the reservoir with a polymeric material capable of releasing the formulation, as suggested in reference '066, e.g. urethane material or polyethylene.

The pore sizes are disclosed n '255. it would have been obvious to on skilled in the art at the time the invention was made to select the polymeric membrane with pores within the range suggested in '255, depending on the degree or of release of the composition through the pores of the semi-permeable membrane.

Reference '066 further discloses the vesicle or membrane pore size to be within the membrane pore range claimed in the present invention (column 69, lines 52-60).

Regarding claim 4, the antioxidants, such myristoyl are disclosed in reference '255, discussed above with regard to claim 61.

As to claims 105, 106, 109, adding consistency modifiers/ antioxidants, and or stabilizers to the formulation is suggested in '255 (page 24, claim 50). The specific viscosity is not disclosed, however, one skilled in the art at the time the invention was

made it would have been motivated to adjust the composition or formulation by adding the components and consistency agents at a level that allow a particular viscosity corresponding to a desire degree of formulation release through the membrane, since a at high viscosity lower permeability through he barrier or membrane can be expected. As to claims 102,110-113, the penetrants e.g. to cure the listed decease in claim 2 are disclosed in references '255 and '066 (page 23-24, claim 38 ('255), and columns 18-20). As to claims 37-40 the material vapor transmission rate is inherent of the material pore size, which is disclosed in the references discussed above, e.g. ultrafiltration membrane (see '255).

7. IDS file on 721/04 has been considered a signed copy is attached.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M. Fortuna whose telephone number is (571) 272-1141. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ana M Fortuna
Primary Examiner
Art Unit 1723

AF
March 21, 2005

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